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FOLEY & LARDNER
2029 CENTURY PARK EAST
SUITE 3500
LOS ANGELES, CA 90067

EXAMINER	
PATTON, AMANDA K	
ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,426	REGHABI ET AL.	
	Examiner	Art Unit	
	Amanda Patton	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment dated July 11, 2007 has been acknowledged. In response to Applicant's arguments regarding the argument regarding the election of species and the telephone conversation between Examiner Amanda Patton and Applicant's Attorney Ted Rittmaster, the election of species has been withdrawn. Currently claims 1-58 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42 and 54-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrases "wherein each implantable sensing element of the plurality of sensing elements comprises a respective power supply" of lines 6-7 and "wherein the power supply for each implantable sensing element is configured to supply power independent of the power supply for each other implantable sensing element" of lines 8-10 do not have support in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-41 and 43-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1, lines 4-6, and Claim 26, lines 3-5 recite the phrase "each implantable sensing element of the plurality of implantable sensing elements operable though electrical communication with an external controller via an individual interconnect." It is unclear if this phrase means that there is only one *total* interconnect between all of the sensors or one interconnect between each of the sensors and the external device in a daisy-chained configuration, thus each sensor having its own interconnect.
- Claim 43, lines 3-6 and claim 54, lines 2-4 recite the phrase "each implantable sensing element of the plurality of implantable sensing elements operable though electrical communication with an external controller via a respective individual interconnect of a plurality of individual interconnects." It is unclear if the plurality of individual interconnects are attaching the sensors together or to the external controller.

Examiner wishes to note the inclusion of the phrase "individual" in all of the claims does not add any structural limitation, as the claims are comprising claim and it does not preclude the use of more than one interconnect between each of the sensors or the external device. If Applicant wishes to include other structural limitations as to the connection of individual sensors to each other or to an external controller such limitation must be placed in the claims if supported by the specification.

Claims 1-4, 8, 9, 11-12, 26, 30-31, 33 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Gord et al. (USPN 5,999,848, as previously cited).

Regarding **claims 1-4, 12, and 26**, Gord discloses the claimed method including:

- implanting an implantable sensor at a single site in a patient, (e.g. Figs. 1–4; Col. 7, lines 28–32; Col. 8, lines 35–36), wherein the implantable sensor has a housing within which are disposed a plurality of implantable sensing elements (e.g. Figs. 3A–5C) and wherein the implantable sensing elements are operable though electrical communication with an external controller via an interconnect (e.g. daisy chained interconnects 14 and 16; Figs. 1-4),
- reading an output from at least one of the implantable sensing elements (e.g. column 7, lines 34–41),
- evaluating a patient based on an output read from at least one implantable sensing element (e.g. column 7, lines 36–53);
- wherein a plurality of parameters are read from an implantable sensor at a single site (e.g. column 7, lines 31–34; column 13, lines 23–25),
- evaluating the patient based on the output read from the sensor and administering therapy to a patient based on an output read from at least one implantable sensing element (e. g. column 7, lines 44–45 and 51–53 wherein regulation of the insulin infusion is the therapy being administered).
- wherein at least one of an implantable sensing elements is a biological parameter sensor, a physiological parameter sensor, an analyte sensor (e.g. column 7, lines 30–34).

- and wherein an output read from at least one of the implantable sensing elements is a quantifiable value (e.g. column 7, lines 33–34 and 45–48);

Examiner wishes to note that since the claim is a comprising claim, it does not preclude the use of more than one interconnect between each of the sensors or the external device.

Regarding **claims 8, 9, and 11, 30-31, and 33**, Gord additionally teaches an implantable sensor method wherein reading/evaluating a patient based on an output from at least one of an implantable sensing elements comprises reading an output from an implantable sensing element that responds to glucose (e.g. column 7, lines 30–33 and 45–48), temperature (e.g. column 7, lines 30–34), or pH (e. g. column 7, lines 30–33).

Regarding **claim 43**, Gord additionally teaches each implantable sensing element of the plurality of implantable sensing elements operable through electrical communication with an external controller via a respective individual interconnect of a plurality of individual interconnects (e.g. interconnect 14 and 16).

Claims 1-4, 7, 9, 12, 26, 29, 31, 42, 45, and 49-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Hayashi et al. (USPN 7,025,778).

Regarding **claim 1-4, 7, 9, 12, 26, 29, 31, 42, 45, and 54-55**, Hayashi discloses the claimed method including (e.g. Figure 2; Col. 4, line 49 - Col. 5, line 5):

- implanting an implantable sensor at a single site in a patient (e.g. endovascular graft 10), the implantable sensor having a housing within which are disposed a plurality of implantable sensing elements (e.g. sensors 16 and 116, among others);

- reading an output of a quantifiable value from at least one implantable sensing element from a single site (e.g. temperature measurements, which is a biological and physiological parameter; Col. 5, lines 31-38 or analyte measurements; Col 5, lines 39-49);
- wherein each implantable sensing element comprises a respective power supply and the power supply for each implantable sensing element is configured to supply power independent of the power supply for each other implantable sensing element (e.g. power source 24 for sensors 16-19 and power source 124 for sensors 116-120);
- evaluating the patient based on the output read from the at least one implantable sensing element and administering therapy based on the measurements (e.g. detecting anomalies; Col. 5, lines 48-49); and
- wherein each implantable sensing element of the plurality of implantable sensing elements is operable through an electrical communication with an external controller via a respective individual interconnect of a plurality of individual interconnects (e.g. sensor 16 wirelessly communicates with external receiver through transmitter 22 and sensor 116 wirelessly communicates with external receiver 116, each of with are "individual interconnects" of a "plurality of interconnects"). Examiner wishes to not that an "individual interconnect" need not be a physical connection, and the wireless communication paths taught in Hayashi fulfill the limitations of the claims.

Regarding **claim 49-50**, Hayashi additionally teaches that each individual interconnect does not pass though any other implantable sensing elements of the plurality of implantable sensing elements, as a wireless transmission allows the most direct access between the receiver and the transmitter, which would not pass through other sensors.

Regarding **claims 51-53**, Hayashi additionally teaches an external controller external to the housing (e.g. receiver not shown, Col. 5, lines 4-5), wherein the individual interconnect between each implantable sensing element of the plurality of implantable sensing elements and the external control is separate from all other individual interconnects for every other implantable sensing element of the plurality of implantable sensing elements on a corresponding communication path from the implantable sensing element of the external controller (e.g. wire communication as described above).

Regarding **claims 56-58**, Hayashi additionally teaches transmitters 22 and 122 that can be considered electrical conductors that extend out of the housing and are electrically connectable to a remote device outside the housing or a controller.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-7, 10, 13-25, 27-29, 32, 34-41, and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gord.

Regarding **claims 5-7, 10, 13-25, 27-29, 32, 34-41, and 44-48**, Gord discloses the claimed invention but does not disclose expressly reading/evaluating a patient based on an output from at least one of the implantable sensing elements comprises reading an output from an implantable sensing element that responds to lactate, blood oxygen saturation, blood pressure, and potassium; and administering therapy/evaluating the patient comprises administering therapy/evaluating the patient for myocardial infarction, myocardial ischemia, angina, adjusting a function and placement of an implantable cardiovascular defibrillator disposed within the patient, sepsis, septic shock, a patient receiving extracorporeal membrane oxygenation, a patient undergoing cardiac bypass, a patient during dialysis; and classifying a severity of a condition of a patient based on an output read from at least one implantable sensing element; and a patient is in a surgical and an intensive care environment; and implanting an implantable sensor at a single site in a triage patient and in a patient in the field. It would have been an obvious matter of engineering design choice to a person of ordinary skill in the art to modify the implantable sensing elements to sense/evaluate the biological and physiological parameters and administer/evaluate therapy to a patient as taught by Gord, to include those parameters and therapies listed in the claimed limitations above, because Applicant does not disclose that these limitations provide an advantage or solves a stated problem over and above the like/similar

claimed limitations listed in the 35 U.S.C. 102(b) rejection over Gord above. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the claimed limitations as taught by Gord, because each of these sensors are configured to sense a different parameter and any configuration of an implantable, daisy-chainable device allows one or more, e.g., multiple, sensors to be employed within the device, with the data sensed by each sensor being convertible to an appropriate form and transferable through conductors to perform a desired medical function as needed for the benefit of the patient. Therefore, it would have been an obvious matter of design choice to modify the invention of Gord to obtain the invention as specified in the claims listed above.

In the alternative, for the above mentioned sensing elements, therapy, and the environment and location of a patient it is well known in the art for sensing elements to respond to lactate, blood oxygen saturation, blood pressure, etc., and to administer therapy for myocardial infarction, myocardial ischemia, angina, etc., and for patients to be in surgery, triage, etc. for the purpose of providing a myriad of beneficial and appropriate therapies to patients efficaciously and expeditiously in a variety of conditions and settings. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Gord to include the claimed limitations above for the purpose of providing a myriad of beneficial and appropriate therapies to patients efficaciously and expeditiously in a variety of conditions and settings.

Claims 5-6, 8, 10-11, 13-25, 27-28, 30, 32-41, 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayashi.

Regarding **claims 5-6, 8, 10-11, 13-25, 27-28, 30, 32-41, 44-48**, Hayashi discloses the claimed invention but does not disclose expressly reading/evaluating a patient based on an output from at least one of the implantable sensing elements comprises reading an output from an implantable sensing element that responds to lactate, blood oxygen saturation, glucose, potassium, or pH; and administering therapy/evaluating the patient comprises administering therapy/evaluating the patient for myocardial infarction, myocardial ischemia, angina, adjusting a function and placement of an implantable cardiovascular defibrillator disposed within the patient, sepsis, septic shock, a patient receiving extracorporeal membrane oxygenation, a patient undergoing cardiac bypass, a patient during dialysis; and classifying a severity of a condition of a patient based on an output read from at least one implantable sensing element; and a patient is in a surgical and an intensive care environment; and implanting an implantable sensor at a single site in a triage patient and in a patient in the field. It would have been an obvious matter of engineering design choice to a person of ordinary skill in the art to modify the implantable sensing elements to sense/evaluate the biological and physiological parameters and administer/evaluate therapy to a patient as taught by Hayashi, to include those parameters and therapies listed in the claimed limitations above, because Applicant does not disclose that these limitations provide an advantage or solves a stated problem over and above the like/similar claimed limitations listed in the 35 U.S.C. 102(e) rejection over Hayashi above. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the claimed limitations as taught by Hayashi, because each of these sensors are configured to sense a different parameter and any configuration of an implantable, daisy-chainable device allows one or more, e.g., multiple, sensors to be employed within the device,

with the data sensed by each sensor being convertible to an appropriate form and transferable through conductors to perform a desired medical function as needed for the benefit of the patient. Therefore, it would have been an obvious matter of design choice to modify the invention of Hayashi to obtain the invention as specified in the claims listed above.

In the alternative, for the above mentioned sensing elements, therapy, and the environment and location of a patient it is well known in the art for sensing elements to respond to lactate, blood oxygen saturation, blood pressure, etc., and to administer therapy for myocardial infarction, myocardial ischemia, angina, etc., and for patients to be in surgery, triage, etc. for the purpose of providing a myriad of beneficial and appropriate therapies to patients efficaciously and expeditiously in a variety of conditions and settings. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Hayashi to include the claimed limitations above for the purpose of providing a myriad of beneficial and appropriate therapies to patients efficaciously and expeditiously in a variety of conditions and settings.

Response to Arguments

Applicant's arguments with respect to claims 1-58 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Patton whose telephone number is (571) 270-1912. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/AKP/
Examiner, Art Unit 3762

/George R Evanisko/
Primary Examiner, Art Unit 3762